EXPRESS MAIL LABEL NO. EV 333 998 313 US

RESPONSE TO RESTRICTION REQUIREMENT & SUPPLEMENTAL PRELIMINARY AMENDMENT	Application No.	10/049,556
	Confirmation No.	7597
	Filing Date	May 7, 2002
	First Named Inventor	LITTLE, DAVID GRAHAM
	Examiner	CRIARES, THEODORE J.
	Group Art Unit	1617
Address to: Commissioner of Patents and Trademarks Washington, D.C. 20231	Docket No.	RICE-006

Sir:

This is in response to the Restriction Requirement dated June 23, 2003. The Examiner therein required election of one of the following groups of claims:

Group I: Claims 41-71, promoting new bone growth at a fractured site and drawn to a method of treating Alzheimer's disease; or

Group II: Claims 29-40, drawn to pharmaceutical compositions.

Applicants hereby elect to prosecute the claims of Group I, claims 47-71, without traverse. Applicants expressly reserve the right under 35 USC §121 to file a divisional application directed to the non-elected subject matter or any subject matter disclosed in this application during the pendency of this application.

AMENDMENTS

In addition, prior to examination of the application on the merits, Applicants request that claims 29-47 be cancelled without prejudice and that new claims 72-83 be added. With the amendments made herein, the current status of the claims is as follows:

1.-47. (Cancelled)

48. (Previously Presented) A method for treating a fractured bone, the method including administering to a subject with a fractured bone a therapeutically effective amount of a drug selected from the group consisting of at least one bisphosphonate.

49. (Previously Presented) The method of claim 48 wherein the drug is administered to the subject as a single dose.

50. (Previously Presented) The method of claim 49 wherein the single dose of drug is administered at an early stage of treatment of the fractured bone.

51. (Previously Presented) The method of claim 48 wherein the mode of administration is as a perioperative intravenous infusion.

52. (Previously Presented) The method of claim 48 wherein the mode of administration is oral.

53. (Previously Presented) The method of claim 48 wherein the mode of administration is transdermal.

54. (Previously Presented) A method of treating a fractured bone, the method including the steps of:

(a) administering to a subject with a fractured bone a therapeutically effective amount of a drug selected from the group consisting of at least one bisphosphonate; and

(b) providing a vibratory stimulus to the fractured bone.

55. (Previously Presented) The method of claim 54 wherein the vibratory stimulus is provided by ultrasound stimulation or vibration stimulation.

56. (Previously Presented) The method of claim 54 wherein the vibratory stimulus includes periodically providing a vibratory stimulus at the resonant frequency of the bone.

57. (Previously Presented) The method of claim 55 wherein the vibratory stimulus includes periodically providing a vibratory stimulus at the resonant frequency of the bone.

58. (Previously Presented) The method of claim 56 wherein the resonant frequency is calculated as a function of the bone's vibratory response to the vibratory stimulus.

59. (Previously Presented) The method of claim 54 wherein the vibratory stimulus is provided at a late stage in the treatment of the fractured bone.

60. (Previously Presented) The method claim 54 wherein the step of providing a vibratory stimulus is concurrent with the step of administering a therapeutically effective amount of the drug.

61. (Previously Presented) The method of claim 60 wherein the vibratory stimulus is provided and the therapeutically effective amount of the drug is administered at an early stage in the treatment of a fractured bone.

62. (Previously Presented) A drug selected from the group consisting of at least one bisphosphonate when used for promoting new bone formation at a fracture site in an individual suffering from delayed union of a fracture.

63. (Previously Presented) A method for promoting new bone formation at a fracture site in a subject suffering from delayed union of a fracture, the method including administering to the subject a therapeutically effective amount of a drug selected from the group consisting of at least one bisphosphonate.

64. (Previously Presented) The method of claim 63 wherein the at least one bisphosphonate

is administered parenterally as a single dose at or near the time of surgery.

65. (Previously Presented) The method of claim 64 wherein a further parenteral dose of the at least one bisphosphonate is administered about four to six weeks after the initial dose.

66. (Previously Presented) The method of claim 64 wherein further oral doses of the at least one bisphosphonate are administered in a daily or second daily regimen commencing about four to six weeks after the initial dose for a period of about two months or until sufficient new bone has been formed.

67. (Previously Presented) A method of promoting new bone formation in a subject, the method including the steps of surgically performing the procedure of distraction osteogenesis and administering to the subject a drug selected from the group consisting of at least one bisphosphonate.

68. (Previously Presented) The method of claim 67 wherein the at least one bisphosphonate is administered parenterally as a single dose at or near the time of surgery.

69. (Previously Presented) The method of claim 68 wherein a further parenteral dose of the at least one bisphosphonate is administered either at the end of the distraction period or up to three months after the initial dose.

70. (Previously Presented) The method of claim 68 wherein further oral doses of the at least one bisphosphonate are administered in a daily, second daily or weekly regimen.

71. (Previously Presented) The method of claim 70 wherein the regimen commences about one to three months after the initial parenteral dose for a period of about two months.

72. (New) The method of claim 48 wherein the therapeutically effective amount of drug promotes new bone formation at the fracture site.

73. (New) The method of claim 48 wherein the drug is Zoledronate.

74. (New) The method of claim 48 wherein the drug is a combination of two or more bisphosphonates.

75. (New) The method of claim 54 wherein the therapeutically effective amount of drug promotes new bone formation at the fracture site.

76. (New) The method of claim 54 wherein the drug is Zoledronate.

77. (New) The method of claim 54 wherein the drug is a combination of two or more bisphosphonates.

78. (New) The method of claim 63 wherein the therapeutically effective amount of drug promotes new bone formation at the fracture site.

79. (New) The method of claim 63 wherein the drug is Zoledronate.

80. (New) The method of claim 63 wherein the drug is a combination of two or more bisphosphonates.

81. (New) The method of claim 67 wherein the therapeutically effective amount of drug promotes new bone formation at the fracture site.

82. (New) The method of claim 67 wherein the drug is Zoledronate.

83. (New) The method of claim 67 wherein the drug is a combination of two or more bisphosphonates.

Formal Matters

Claims 48-83 are pending after entry of the amendments set forth herein.

Claims 1-28 were previously cancelled in a Preliminary Amendment filed with the application.

By this Supplemental Preliminary Amendment, claims 29-47 have been cancelled without prejudice and claims 72-83 have been added.

The newly presented claims are supported by the specification and at least by originally filed claims 5, 7 and 9 (previously cancelled). Accordingly, no new matter has been added.

Applicants respectfully request consideration of the application and allowance of the claims in view of the amendments and remarks made herein.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number RICE-006.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: Dec. 22, 2003

By: _____
Carol M. LaSalle
Registration No. 39,740

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENT\RICE\006\resp restr reqment.rtf